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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,019

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EXAMINER

BADR, HAMID R

ART UNIT

PAPER NUMBER

1781

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,019	<b>Applicant(s)</b> ZIRZOW ET AL.	
	<b>Examiner</b> HAMID R. BADR	<b>Art Unit</b> 1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 32-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' amendment filed 6/24/2010 is acknowledged.

The rejection under 35 U.S.C. 101 (use claims) is withdrawn per Applicants' cancellation/amendment of claims.

Claims 32 – 46 are being considered on the merits.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 34, 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 34 is indefinite for “blood sugar values are determined from fasting blood sugar values”. It is not clear whether the blood sugar is determined in fasting individuals which is a norm in the art, or certain values in fasting individuals are picked up and reported.

4. Claim 35 is indefinite for “associated forms and/or performs”. It is not clear what this phrase is referring to.

#### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 32-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Tolle (WO/2001/010245, US 6,706,294 is an English equivalent of this publication.; hereinafter R1).

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6. R1 discloses the full process of fermenting the distillers grains with yogurt or butter cultures. The processing steps are disclosed as presently claimed in claim 38. (col. 1, lines 22-37).

7. R1 teaches of dosing quantities of 21-25 grams to be effective doses. R1 discloses that 135 g of the fermented mass having 17% dry matter would provide the required dose. R1 then teaches of mixing the effective dose with other foods including milk preparations that can be presented in portions of 200-250 g ready to consume units. (col. 1, lines 50-60).

8. R1 discloses that the fermented product is suitable for diabetics (col. 2, line 11), for slimming cures, for recovery after operations, for dietetic foods, for the treatment of amino acid deficiency, for pancreatic functional disorders, carbohydrate addiction diseases, for intestinal functional disorders (col. 2, lines 55-61), for diabetics and weight reduction (col. 2, lines 47-48).

9. R1 discloses the inventive product can also be used as a supplementary diet during slimming cures (col. 2, lines 55-56). The consumption of the product as a food supplement as disclosed by R1 (col. 3, lines 10-15) is also an indication that the product is consumed on a steady basis for a period of time. It is clear that as a supplement the preparation would be consumed for a predetermined period of time during which the blood sugar level as well as blood triglyceride level would decrease therefore, the method as presently claimed would be inherent in the consumption of the fermented preparation when used as a supplement.

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10. Given that R1 discloses utilizing the fermented distillers grains for the reduction of diabetic effects (i.e. reducing blood sugar level) and weight reduction, and clearly both of these abnormalities are long term health problems, the reduction of effects will also be a long term issue for which a long term consumption of the fermented product is anticipated. The long term consumption of the product will be in fact the method as presently claimed.

11. R1 discloses that it is possible to provide the product with further fermentable additives such as lecithins, honey, soybean proteins. (col. 2, lines 27-30).

12. R1 also discloses the incorporation of the fermented product into other foods. (Claims 9- 11).

### ***Response to Arguments***

Applicants arguments are not persuasive for the following reasons.

1. Applicants argue that R1 does not disclose a method for treating increased blood sugar by administering a composition comprising the fermented distillers grains.

a. R1 clearly discloses the usefulness of their inventive product for diabetic people, for overweight people etc. R1 further teaches of using the product as a supplement which means that the product be consumed on a regular basis at least for a certain period of time. It is clear that the lowered blood sugar and lowered triglyceride levels will be inherent to the consumption of the product on a regular basis. The net effect will be the method as presently claimed.

2. Applicants argue that R1 discloses a process in which the distillers grains, after fermenting with yogurt culture, will no longer exhibit disturbing flavors and that a person

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in the art does not obtain any motivation from R1 to treat patients suffering from increased blood sugar.

a. It should be realized that having pleasant flavor is a property of the fermented product. Additionally R1 discloses the determination of an effective dose which of course does not have anything to do with the improved flavor of the product. R1 also mentions the word "actives", therefore, the product must have some kind of nutritional/medicinal use.

Furthermore, it should be emphasized that the product is a food not a drug. The clinical studies carried out by Applicants is simply the provision of the fermented product on a regular bases to individuals with elevated blood sugar which is exactly taught by R1 when they teach using the food as a supplement for people with metabolic abnormalities.

Additionally, the effects of consuming the fermented product of R1 are anticipated not obvious to be motivated or not.

Applicants are referred to the following passage.

**PROCESS OF USE CLAIMS — NEW AND UNOBVIOUS USES OF OLD STRUCTURES AND COMPOSITIONS MAY BE PATENTABLE**

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). **However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated.** In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) (Claims 1 and 6, directed to a method of effecting nonaddictive analgesia (pain reduction) in animals, were found to be anticipated by the applied prior art which disclosed the same compounds for effecting analgesia but which was silent as to addiction. The court upheld the rejection and stated that the applicants had merely found a new property of the compound and such a discovery did not constitute a new use. The court went on to reverse the rejection of claims 2-5 and 7- 10 which recited a process of using a new compound. The court relied

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on evidence showing that the nonaddictive property of the new compound was unexpected.). See also *In re Tomlinson*, 363 F.2d 928, 150 USPQ 623 (CCPA 1966) (The claim was directed to a process of inhibiting light degradation of polypropylene by mixing it with one of a genus of compounds, including nickel dithiocarbamate. A reference taught mixing polypropylene with nickel dithiocarbamate to lower heat degradation. The court held that the claims read on the obvious process of mixing polypropylene with the nickel dithiocarbamate and that the preamble of the claim was merely directed to the result of mixing the two materials. "While the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the old composition." 363 F.2d at 934, 150 USPQ at 628 (emphasis in original).)

### ***Conclusion***

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R. Badr  
Examiner  
Art Unit 1781

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1781